



# SIMONETTA

di Lento Filippo

dal 1908

## CONTENITORI VETRO e PLASTICA

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**OGGETTO : dichiarazione conformità dei FLACONI BOCCA LARGA POLITENE  
SIGILLO (con tappo margherita) alle specifiche previste dalla  
Farmacopea Ufficiale XI Ediz.**

Con la presente Vi specifichiamo la composizione dei sopra citati contenitori:

**SERIE FLACONI BOCCA LARGA POLITENE SIGILLO CON TAPPO** : la materia prima che li compone è il POLIETILENE (PE) ed in particolare il "Lupolen 2426F"  
Alleghiamo le schede del fornitore della materia prima (BASELL) da cui risulta la conformità del materiale alle specifiche previste da :

-EP IV Ed. - parag. 3.1.3 POLIOLEFINE

Distinti saluti.

Ditta SIMONETTA  
di Lento Filippo

**Regulatory Affairs Product Stewardship Information / Certification**  
**Data Sheet**  
**(RAPIDS)**

**Lupolen 2426 F**

**Product Manufacturer**

This product is manufactured by Basell Europe.

**Chemical Inventories**

All ingredients in this product are in compliance with the following chemical inventories:

United States: Toxics Substances Control Act Inventory (TSCA)

Canada: Domestic Substances List (DSL)

Europe: European Inventory of Existing Chemical Substances (EINECS)

Australia: Australian Inventory of Chemical Substances (AICS)

Korea: Korean Existing Chemicals List (KECL)

Japan: Japanese Inventory (ENCS)

Philippines: Philippines Inventory of Chemicals and Chemical Substances (PICCS)

This product has no special requirements under US TSCA (e.g. consent orders, test rules, 12(b) requirements, etc.).

**Food Contact**

European Union (EU) Food Contact

The composition of this product complies with the following Legislations, Recommendations or Communications for the production of food packaging.

AUSTRIA: "K.V.O." NÂ°775, 23/09/1994 as amended at last by BGBl 14/10/2003 - Teil. II - n.476

BELGIUM: "Arrete royal du 10 decembre 2002 (amending Arrete royal du 11 mai 1992).

DENMARK: Foededirektorates Bekendtgorelse NÂ° 111 (20/02/2003).

FINLAND: "KTM", Paatos 953/2002 of 12.11.2002.

FRANCE: "Materiaux au contact des aliments et de denre destine a l'alimentation humaine" Brochure n.1227 edition Janvier 1994 as updated. Arrete du 14 Septembre 1992 (as modified at last by Arrete 02/01/2003).

GERMANY:

Bedarfsgegenstandeverordnung- 7 April 2003

BfR is no longer applicable for this resin

GREECE: AXE Decision n.458/2002

IRELAND: Statutory Instruments NÂ°542 of 2002.

ITALY: "Decreto Ministeriale del 21/03/1973" amended on 26/4/1993 : D.M. N.220 and following updates (last update: D.M. N.123 of 28/03/2003).

LUXEMBOURG: "Reglement Grand-Ducal" du 27/01/2001.

NORWAY: "Kongelig resolusjon" of 11 March 1976 and updated 21/12/1993.

PORTUGAL: "Decreto Lei" N.4/2003 of 10/01/2003.

SPAIN: Resolucion de 04/11/1982 amended by Real Decreto 442/2001.

SWEDEN: Food regulation SLV FS 1993:18 as updated by SLV FS 2003:2.

THE NETHERLANDS: " Staatscourant n.183 of 24.09.2002.

UNITED KINGDOM: "Plastics for food contact applications" Revised Ed.1986. Statutory Instruments, 1992 N.3145 and followings updates (last update: S.I. 2002/N.3008).

SWITZERLAND: KsV, 26 June 1995 as modified by KsV, 30/01/1998.

CZECH REPUBLIC: Regulation of the Ministry of Health N.38/2001

The monomers used to produce the resin are listed in EU Directive 2002/72 without any use limitations.

The additives for which a Qm is specified by the regulations are the responsibility of Basell.

There are NO SMLs specified by the regulations for the additives in this resin.

EU Directive 2002/72/EC , which applies to all EU Member States, specifies 10 mg/dm<sup>2</sup> as the maximum overall migration from finished plastic food contact articles. This is the responsibility of the converter.

In accordance with EU Directive 2002/72/EC the migration should be measured using the actual foodstuff or the appropriate food simulants at the real time/temperature conditions of use, according to the rules specified in EU Directives 97/48/EC (amending 82/711/EC) and 85/572/EC.

We remind you that the users must verify that the finished items, manufactured according to good technology practice, must not modify the organoleptic properties of the food.

#### US Food and Drug Administration (FDA)

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(2)(i) and (c)2.1, 2.2. According to our information, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b). This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

#### **Tallow**

Tallow derived additives are not used in the manufacture of this product.

#### **Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)"/"Mad Cow"**

We do not use components derived from animal sources in the manufacture of or formulation of this product.

#### **Kosher**

We do not certify our resins to be Kosher or in compliance with Kosher requirements.

#### **Drug Master File (DMF)**

Information on this product is listed in DMF N. 12311. Contact Basell for a DMF authorization letter to be sent to FDA.

### **European Pharmacopeia (EP)**

The composition is in compliance with monographs 3.1.3 4th Edition of European Pharmacopeia

### **US Pharmacopeia (USP)**

This product has not been tested for USP Class VI.

### **Latex**

"Natural rubber latex", "dry natural rubber", "synthetic latex" or "rubber that contains natural rubber" are not used in the manufacture of or the formulation of this product.

### **Heavy metals (ELV Directive 2000/53/EC)**

The quantity (statistically evaluated) of Cd, Pb, Cr, Hg present in this grade is deemed below the limits given in Annex II (Note) of the Decision 2002/525/EC of June 27th (amending Annex II of Directive 2000/53) which establishes: 0.1% Lead 0.1% Chromium 0.1% Mercury 0.01% Cadmium

### **Coalition of Northeastern Governors (CONEG)**

Cadmium, chromium, lead and mercury are not used in the manufacture of or the formulation of this product. In addition, this product meets the CONEG requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury.

### **European Union (EU) Directive - Packaging and Packaging Waste - 94/62/EC (as amended)**

Cadmium, chromium, lead and mercury are not used in the manufacture of or the formulation of this product. This product meets the year 2001 requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury. In addition, this product has the potential to be recycled according to these requirements.

### **California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)**

This product presents "no significant risk" to the people of California. This product contains no substances known to the State of California to cause reproductive toxicity at a level of exposure subject to the requirements of Proposition 65.

### **Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)**

BHT and BHA are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

### **Ozone Depleting Chemicals (ODCs)**

Class I and Class II ODCs listed in the Resolution 2037/2000/EC are not used in the manufacture of or formulation of this product.

### **Toys**

This product complies with the requirements in CEN Standard EN71.3.

The phthalates listed in article 1 of Decision 1999/815/EC are not intentionally added in the manufacture of or the formulation of this product. The phthalates are: DINP ( di-iso-nonyl phthalate) DEHP (di-(2-ethylhexyl) phthalate) DBP (di-n-butyl phthalate) DIDP (di-iso-decyl phthalate) DNOP ( di-n-octyl phthalate) BBP (butylbenzyl phthalate)

### **Phthalates**

The phthalates listed in Italian Ministry of Health Decree no538, dated December 17, 1999, are not intentionally added in the manufacture of or the formulation of this product. The phthalates are: DINP ( di-iso-nonyl phthalate) DEHP (di-(2-ethylhexyl)phthalate) DBP (di-n-butyl phthalate) DIDP (di-iso-decyl phthalate) BBP (butylbenzyl phthalate) DIOP ( di-iso-octyl phthalate) DEP (di-ethyl phthalate) DCHP (di-cyclo-hexyl phthalate) DMCHP ( di-methyl-cyclo-hexyl phthalate) DMEP (di-methoxy-ethyl phthalate)

### **Acrylamide**

Acrylamide (CAS number 79-06-1) is not used in the manufacture of or the formulation of this product. However, we do not test this product for acrylamide.

### **Aromatic Amines**

Aromatic amines are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

### **Asbestos**

Asbestos is not used in the manufacture of or formulation of this product. However, this product has not been tested for this chemical substance.

### **Bisphenol A**

Bisphenol A is not used in the manufacture of or the formulation of this product. However, this product has not been tested for this chemical substance.

### **Dioxin**

Dioxin is not used in the manufacture of or formulation of this product. Dioxin is not known to be formed during processing of this product.

### **Epichlorohydrin**

Epichlorohydrin (CAS number 106-89-8) is not used in the manufacture of or the formulation of this product. However, we do not test this product for epichlorohydrin.

### **Nonylphenol**

Nonylphenol is not used in the manufacture of or the formulation of this product. However, this product has not been tested for this chemical substance.

### **Organo-tin Compounds**

Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds are not used in the manufacture of or the formulation of this product.

### **Polychlorinated Biphenyls (PCBs) ,Polybrominated biphenyls (PBBs), Polychlorinated Terphenyls (PCTs), Polybrominated diphenyl ether (PBDE) and Polybrominated Terphenyl (PBT)**

Polychlorinated biphenyls (PCBs), polybrominated biphenyls (PBBs), polychlorinated terphenyls (PCTs), polybrominated diphenyl ethers (PBDEs) and polybrominated terphenyls (PBTs) are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

### **Vinyl Chloride**

Vinyl chloride (CAS number 75-01-4) is not used in the manufacture of or the formulation of this product. However, we do not test this product for vinyl chloride.

### **BADGE/NODGE/BFDGE**

BADGE, NODGE and BFDGE are not used in the manufacture of or the formulation of this product.

### **Epoxy Resins - Directive 2002/16/EC**

Epoxy resins are not used in the manufacture of or the formulation of this product.

### **Switzerland "VOC-LENKUNGSABGABE"**

This product contains less than 3% VOC's of the substances in the positive lists of the above Regulations

### **Composting - CEN Standard prEN 13432**

This product is not suitable for composting

**Energy Recovery - CEN Standard prEN 13431**

The calorific gain from polyethylene in an energy recovery process is 22 MJ/Kg

**Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications. This certificate shall continue in effect for 1 year from its effective date unless it is modified before. If, during such 1 year period, Basell changes the product formulation such that the RAPIDS is no longer accurate, Basell will notify you ( normally by e-mail). Basell shall not notify you in case changes in the regulations occur. Basell recommends that customers continuing to use our product verify status frequently and at least every year from the issue date of the RAPIDS.**

Certified for Basell by:



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Approved on Tuesday, September 16, 2003. Valid for 1 year unless modified before.